

REMARKS

Telephone Interview

Applicants would like to thank Examiner Ware and Examiner Naff for the courtesy extended to Applicants' agent, Angela Dallas Sebor, during the telephone interview of June 15, 2005. During the interview, the rejections under 35 U.S.C. § 112, first and second paragraph, and 35 U.S.C. § 101, were discussed. With regard to the rejection under 35 U.S.C. § 112, first paragraph, the Examiners acknowledged that the Declaration by Dr. Sebor affirming the Deposit was already received with the Preliminary Amendment filed on February 2, 2005, but suggested that the specification be amended to reflect the deposit of microorganisms. With regard to the rejection under 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 101, the term "isolated" was discussed with respect to the Examiner's suggestion to replace the term with "biologically pure". The Examiners suggested that Applicants point to other issued patents that have use the term "isolated" with reference to a microorganism that is not a recombinant microorganism and further suggested that any other evidence in favor of the presently recited term be provided for consideration.

Objection to the Specification and Rejection of Claims 43-54 Under 35 U.S.C. § 112, First Paragraph:

The Examiner has objected to the specification and rejected Claims 43-54 under 35 U.S.C. § 112, first paragraph, contending that the specification indicates that the claimed microorganisms have been deposited but does not provide evidence as to the public availability. The Examiner states that a statement by a registered agent or attorney assuring the compliance with the terms of the Budapest Treaty would satisfy the deposit requirement.

In the June 15 telephone interview, Applicants' agent noted that the requisite Declaration regarding the deposit under the terms of the Budapest Treaty had already been submitted with the Preliminary Amendment on February 2, 2005, and the Examiner acknowledged that this document was in the file. The Examiner asked in the interview that the specification be amended to refer to the deposit.

In reply, it is noted that the original deposit was referenced in the specification on page 18, but the specification has now been amended to more specifically reference the deposit according to 37 CFR 1.809(d) and to include all five of the deposited microorganisms.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 43-54 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 43-54 Under 35 U.S.C. § 101:

The Examiner has rejected Claims 43-54 under 35 U.S.C. § 101, contending that it is unclear that the claimed microorganisms are isolated from nature since the term "isolated" is used in place of "biologically pure". The Examiner suggests that the term "isolated" be changed to "biologically pure". In the June 15 interview, the Examiners expanded on this rejection by asserting that the term "isolated" may not reflect removal from nature or manipulation by the hand of man. The Examiners stated that the most of the Examiners in their group art unit have decided that the phrase "biologically pure" is more representative of removal of a microorganism from nature, although it was acknowledged that at least one Examiner accepts the term "isolated". The Examiners suggested that the term "biologically pure" was more reflective of a microorganism that has been removed from nature.

The rejection under 35 U.S.C. § 101 is respectfully traversed. It is submitted that the Examiner's suggested term, "biologically pure", is neither a necessary nor a reasonable substitute for the term "isolated". The Examiners have not provided any documentation or written policy regarding what the Patent Office considers to be the meaning of this term, and since the term is not used in the present specification, it is unreasonable and inappropriate to suggest that the term be used to replace the term "isolated", the meaning of which is clear from the present specification. Applicants are allowed to be their own lexicographers, and in this case, the choice of terminology is in no way contrary to the commonly accepted meaning of the term, nor to the intent of 35 U.S.C. § 101. First, it is submitted that the term "isolated" is well understood in the art and in the general public, and that one of skill in the art would be apprised based on the use of the term in the specification that the claimed microorganism is isolated from nature (the product of human

ingenuity). Indeed, in making the rejection on the basis that the term "isolated" is unclear, the Examiner *uses the same term* to describe what she believes should be conveyed by the preamble: "[i]t is unclear that the claims are isolated from nature since the term "isolated" is used in place of --biologically pure--" (emphasis added).

Second, the term "isolated" or "isolate" is used throughout the present specification to describe the microorganisms of the invention, such that it would be clear to one of skill in the art that the claimed microorganisms are a product of human ingenuity (the handiwork of man). Indeed, to *isolate* the microorganisms of the invention according to the present invention (*e.g.*, see page 8, line 20 to page 9, line 8; or page 17, lines 15-20), one uses collection, filtering, culturing and selection steps (*e.g.*, see Example 1) that are quite clearly human handiwork and include the removal of the microorganisms from nature.

Third, the claims are directed to specific microorganisms and strains derived therefrom. The claimed microorganisms were deposited with the American Type Culture Collection. In order to deposit a microorganism with the American Type Culture Collection, the microorganism must be isolated from nature in a form that can be characterized and cultured. Therefore, the specification is clear regarding the meaning of the term "isolated" such that the statutory subject matter of the presently claimed invention should be acknowledged.

Finally, the Patent Office clearly recognizes that the term "isolated" is sufficient to describe statutory subject matter related to microorganisms by the recent issuance of at least five patents that claim "An isolated microorganism" (see U.S. Patent Nos. 6,800,474; 6,716,615; 6,642,031), "An isolated bacteria strain" (see U.S. Patent No. 6,833,259) or "An isolated bacterium" (see U.S. Patent No. 6,605,461). It is noted that the claims in these patents recite deposited microorganisms, and do not appear to recite recombinant microorganisms. Copies of these patents are enclosed for the Examiners' convenience.

In view of the foregoing discussion, the Examiner is respectfully requested to withdraw the rejection of Claims 43-54 under 35 U.S.C. § 101.

Rejection of Claims 43-54 Under 35 U.S.C. § 112, Second Paragraph:

The Examiner has rejected Claims 43-54 under 35 U.S.C. § 112, second paragraph, contending that these claims are indefinite due to the use of the term "isolated". The Examiner contends that the term is unclear as noted in the rejection under 35 U.S.C. § 101 and suggests that the term be changed to "biologically pure".

The rejection under 35 U.S.C. § 112, second paragraph is respectfully traversed. Initially, the arguments in response to the rejection under § 101 are referenced again here in support of the position that the term "isolated" is clear and definite, particularly in view of the frequent use of the term throughout the present specification. As set forth in MPEP 2173.02: Examiners "should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirements." Also, "Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

In this case, as discussed above, the content of the particular application disclosure is clear with regard to what is meant by the term "isolated" as used in connection with the claimed microorganisms. Moreover, the use of the term is not contrary to the teachings of the prior art and would clearly be understood by those of ordinary skill in the pertinent art to refer to microorganisms that have been removed from nature and are the product of human ingenuity.

In view of the foregoing remarks, the Examiner is respectfully requested to withdraw the rejection of Claims 43-54 under 35 U.S.C. § 112, second paragraph.

*Application No.: 10/789,635*

It is submitted that all of the issues raised by the Examiner in the March 29 Office Action have been addressed, and that the claims in a condition for allowance. In the event that the Examiner has any further questions or concerns regarding Applicants' position, she is encouraged to contact the below-named agent at (303) 863-9700.

Respectfully submitted,

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